

Application No. 09/508,979
Amendment dated July 29, 2003
Response to Office Action mailed January 29, 2003

REMARKS

With the entry of the present Amendment, claims 1, 2, 4-6, 8, 11-57, 64, 65, 67-69, 86-94 and 96-115 are pending in this application. Claims 3, 7, 9-10, 58-63, 66, 70-85, and 95 have been canceled without prejudice, and certain claims have been amended for improved clarity. New claims 102-109, which do not recite a selecting step, are supported by originally filed claims 1, 21, 28, 33, 38, 42, 47 and 52. New claims 110-115 are supported by the examples and the data presented therein. None of the amendments made herein constitutes the addition of new matter.

The Drawings

Applicants respectfully note that Formal Drawings were filed by first class mail December 19, 2001. However, the Patent Drawing Review Form provided with the current Office Action is dated December 19, 2001. Applicants respectfully request consideration of the drawings filed in 2001. In the event that the previously filed Formal Drawings were lost, Applicants provide herewith a copy of the previous submission, together with a copy of the return receipt postcard stamped by the Patent and Trademark Office on January 4, 2002.

The Rejection under 35 U.S.C. 112, first paragraph

Claims 1-2, 4-6, 11-57, 64-65, 67-69, 86-94 and 96-101 have been rejected under 35 U.S.C. 112, first paragraph, as allegedly containing subject matter which was not described in the Specification in such a way as to reasonably convey to one skilled in the art that the inventors, at the time the application was filed, had possession of the invention. Applicants respectfully traverse this rejection.

The claims are drawn to methods of modifying the content or composition of a metabolite in the storage organ of a plant by expressing a sulfur rich protein, determining the composition or content in the storage organ and selecting a plant having the modified composition or content in the storage organ. The Patent Office has alleged that the selecting step is not supported by the Specification.

Claims 1 and 21 have been amended to recite that the sulfur-rich protein encoded by the chimeric gene "is a 2S protein or the Asp1 synthetic protein". Basis for this amendment is contained in original claim 13 and in the original disclosure from page 6, line 30, to page 7, line 4, of the as-filed Specification. The 2S protein family is widespread and is well known to a person skilled in this art. In support, we enclose a copies of two papers, Youle and Huang (1981) "Occurrence of Low Molecular Weight and High Cysteine Containing Albumin Storage Proteins in Oilseeds of Diverse Species," American Journal of Botany 68:44-48 (Exhibit A, submitted herewith) and Shewry *et al.* (1995) "Seed Storage Proteins: Structures and Biosynthesis", The Plant Cell 7:945-956 (Exhibit B, submitted herewith), which describe the widespread knowledge and characterization of S2 sulfur-rich proteins. Please note, for example, that the final section of the introduction of Youle and Huang (1981) at page 44 states: "[T]he results reported in this paper, reveal a distinct class of seed storage protein with a wide distribution". The Shewry *et al.* (1995) paper provides a broad overview of seed storage proteins, including 2S albumin storage proteins.

In addition, the amended set of claims forwarded herewith includes new claims 102 to 109 which "parallel" previous claims, but without the "selecting" step (iii) in those claims. New claims 110 to 115 are also proposed, based on disclosure of specific modifications of metabolite content and/or composition disclosed at page 10, line 25, to page 13, line 4, of the Specification.

Applicants respectfully submit that a person skilled in the art readily understands that in the production of transgenic plants by methods such as the method of the present invention, there would be a range in the extent to which a particular phenotype would be modified in the transgenic plants. Accordingly, faced with a range of modifications of a particular phenotype, the person skilled in the art would select one at a desired extent of modification. Support for this can be found in the present specification by referring, by way of example, to Table 12 on page 42 of the Specification. This Table clearly demonstrates that in various transgenic rice plants which were produced by the method described in Example 4, the level of seed nitrogen in the transgenic plants varied in the range between 1.14 and 1.98 (% dry matter), and was higher than the seed nitrogen level in nontransformed

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rice which was 1.01 (% dry matter). In the light of the results shown in Table 12, it is clear that a person skilled in the art would select a transformed rice line from the various samples in Table 12 for a desired extent of modification of seed nitrogen content. Accordingly, it is submitted that the inclusion of the selecting step (iii) in claim 1 and other independent claims does not constitute "new matter" as asserted by the Examiner, but rather finds support in that a person skilled in the art would understand from the disclosure as a whole that such a selection step would form part of the method of the present invention.

In the interest of advancing prosecution and without acquiescing to the rejection, new claims 102 to 109 are also submitted without the selection step (iii). Clearly, these claims do not include the "new matter" alleged by the Examiner, so this rejection does not apply to these claims.

Claims 1-2, 4-6, 8, 11, 14-27, 65, 67-69, 86-87 and 101 have been rejected under 35 U.S.C. 112, first paragraph, as allegedly containing subject matter which was not described in the Specification in such a way as to reasonably convey to the skilled artisan that the inventors, at the time the application was filed, had possession of the claimed invention. Applicants respectfully traverse this rejection.

The Patent Office has also alleged that the claims "do not recite the specific identity of any particular nucleotide sequence encoding any particular sulfur-rich protein which modifies the content or composition or content and composition, of a metabolite in the storage organ of the plant transformed therewith".

In response to this rejection, claims 1 and 21 have been amended to incorporate the subject matter of previous claim 13, thereby reciting the specific identity of the sulfur-rich protein as a 2S protein or the Asp1 synthetic protein. This amendment is supported by the as-filed Specification, at page 6 line 30 to page 7 line 4. Applicants note that the 2S family of proteins referred to at page 7 line 1 is a distinct class of protein as confirmed by the Youle and Huang (1981) "Occurrence of Low Molecular Weight and High Cysteine Containing Albumin Storage Proteins in Oilseeds of

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Diverse Species," American Journal of Botany 68:44-48 (Exhibit A, submitted herewith) and Shewry *et al.* (1995) "Seed Storage Proteins: Structures and Biosynthesis", The Plant Cell 7:945-956 (Exhibit B, submitted herewith). Furthermore, it is Applicants' position that it is predictable that the proteins of the 2S family of sulfur-rich proteins which were not specifically exemplified in the present methods have equivalent function.

In view of the foregoing and in view of the amendments made herein, Applicants respectfully maintain that the amended claims are enabled by the specific disclosure of sunflower seed albumin (SSA) as a member of the 2S family of proteins.

With respect to the allegation that "the specification only describes one method for making a variety of specific changes (in) the content or composition of a variety of specific metabolites in the seed of transgenic lupin, pea, chickpea and rice plants, said methods comprising transforming the plants with a nucleotide sequence encoding sunflower seed albumin (pages 27-41)", Applicants respectfully note that the specification discloses modification of the content and/or composition of metabolites in the storage organs of a variety of plants; specifically the four representative species acknowledged by the Examiner include both monocotyledons and dicotyledons, and legumes and non-legumes. The Specification provides data obtained using the SSA gene and states that other members of the 2S protein family provide also achieve that stated goal. The Patent Office has provided no evidence or sound scientific reasoning to doubt assertions made by Applicants, as required by In re Marzocchi, 169 U.S.P.Q. 367, C.C.P.A., 1971.

Claims 1-2, 4-6, 8, 11-57, 64-65, 67-69, 86-94 and 96-101 have been rejected as allegedly not enabled for methods as broadly as claimed. Applicants respectfully traverse this rejection.

The Patent Office has alleged that the Specification does not disclose methods for altering content or composition of a storage organ other than a seed or the use of a sulfur rich protein other than that of SSA. It has been alleged that the Specification does not provide sufficient guidance for one skilled in the art to determine which sulfur rich proteins to use.

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Applicants respectfully submit that the level of skill in the art of plant molecular biology is high. The 2S family of proteins is well known to the art, as discussed above. One of ordinary skill in the art can use art-known sequences in readily available vectors for the genetic modification of a plant of interest to modify the nutritional content of a storage organ. The art also knows transcriptional regulatory sequences which direct expression in the targeted organ. Thus, the genetic modification of a plant using a 2S protein to change the content of a particular parameter in a storage organ, such as a seed, is well within the abilities of the ordinary skilled artisan in the relevant art, and the practice of the invention will not require undue experimentation.

In view of the foregoing, Applicants submit that adequate teachings are provided, and the withdrawal of the rejection is respectfully requested.

The Rejections under 35 U.S.C. 112, second paragraph

Claims 1, 5-6, 8, 21, 28, 31-33, 38, 42, 46, 47, 50-52, 56-57, 88-91, 93, 94 and 101 have been rejected under 35 U.S.C. 112, second paragraph, as allegedly indefinite for failing to particularly point out and distinctly claim the subject matter Applicants regard as the invention. Applicants respectfully traverse this rejection.

Claims 1, 6, 28, 32, 33, 38, 42, 47, 50, 52, 56, 89, 90, 91, 92, 93, 94 and 101 are allegedly indefinite in the recitation of modifying or modified, increasing or increased, decreasing or decreased, for lacking a comparative basis. Claims 5, 8, 21, 31, 46, 51, 57, 88, 90 and 93 are allegedly indefinite for the recitation of a comparative basis.

In the interest of advancing prosecution and without acquiescing to the rejection, Applicants have amended the relevant claims to recite comparison to a plant which does not express said chimeric gene.

With respect to the term modified, the Examiner has alleged that it would be unclear how the content or composition is modified –increased, decrease, change in composition, etc. Applicants

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respectfully maintain that the Specification provides various examples of changes, and this is understood in the art.

The expression of the 2S or Asp protein affects more than just the range of proteins expressed in the relevant tissue. The examples provided in the present Specification clearly show this. The terms "increasing" and "increased", and "decreasing" and "decreased" have been objected to on a similar basis.

Applicants respectfully refer the Examiner to the definition of the term "modifying the content and/or composition of one or more metabolites" at page 9, lines 24-29, of the present specification, where the meaning of the term is made abundantly clear to a person skilled in the art. In addition, the description on pages 10 to 13 provides further detailed disclosure of the modification of content and/or composition of various metabolites in accordance with the present invention, and provides a comparative basis for various modifications to these metabolites.

Claims 1 and 101 are allegedly indefinite in the recitation of oil (fatty acid). It is allegedly unclear whether the use of parentheses is intended to limit "oil" to fatty acids only.

In the interest of advancing prosecution and without acquiescing to this aspect of the rejection, claims 1 and 101 have been amended to only recite "fatty acid".

Claim 5 is allegedly indefinite in the recitation of total protein nitrogen, with the base claim said to fail to provide antecedent basis.

In the interest of advancing prosecution, claim 1 has been amended to recite "total" protein nitrogen, thereby providing the requisite antecedent basis for claim 5.

Claim 57 is allegedly indefinite in the recitation of content, with claim 52 said to fail to provide proper antecedent basis.

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In the interest of advancing prosecution and without acquiescing to this aspect of the rejection, Applicants have amended claims 56 and 57 to delete the word "content" and replace with --level of--.

Claim 101 is allegedly indefinite because it is unclear what happens to "at least one of said metabolites" in the selected plant.

In the interest of advancing prosecution and without acquiescing to this aspect of the rejection, claim 101 has been amended to clarify that the claim refers to the modification of the content and/or composition of more than one metabolite, at least one of which is selected from the recited group.

In view of the clarifications provided herein and the amendments to the claims, Applicants respectfully submit that the claims meet the statutory requirements for particularly pointing out and distinctly claiming the subject matter regarded as the invention. Accordingly, the withdrawal of the rejections under Section 112, second paragraph, is requested.

The Rejection under 35 U.S.C. 102 or 103

Claims 1-2, 4-6, 8, 11-17, 19-23, 25-26, 28-31, 33-40, 42-44, 47-50, 52-57, 64-65, 67-69, 86-94 and 96-100 have been rejected under 35 U.S.C. 102(b) as allegedly anticipated by, or in the alternative, under 35 U.S.C. 103(a) as allegedly obvious over Molvig (1997). Applicants respectfully traverse this rejection.

Applicants respectfully note that the previous rejection of the claims under 35 U.S.C. §103 was withdrawn. Again, Applicants respectfully note that Molvig *et al.* contains no disclosure or teaching which is relevant to modification of metabolites selected from the group consisting of fatty acid, starch, soluble non-starch polysaccharide, insoluble non-starch polysaccharide, fibre and total protein nitrogen, as recited, for example, in claim 1. The passage in Molvig *et al.* which the Examiner has relied on does not mention any of the particular metabolites recited in claim 1, and accordingly

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should not be used in an obviousness rejection in the absence of any other teaching or disclosure regarding the modification of any one of those particular metabolites. Case law states that which is unknown cannot render a later invention obvious (*In re Spormann*, 150 U.S.P.Q. 449, C.C.P.A., 1966). For a proper rejection under 35 U.S.C. 102, the claimed invention must clearly follow from the teachings of the cited prior art. Applicants respectfully maintain that this is not the case. There is nothing in the cited Molvig reference which places the instant method claims into the hands of the skilled artisan. Accordingly, the rejection for alleged anticipation is not proper. Molvig *et al.* contains no disclosure or teaching of the step of selecting a plant having a modified content and/or composition as related to these other metabolites in the storage organ thereof, and accordingly Molvig *et al.* clearly does not anticipate claims which recite this selection step. It is noted that the Examiner acknowledges on page 12 of the official action that "Molvig *et al.* is silent with respect to the claim limitations directed to specific metabolites other than amino acids, and with respect to the claim limitation directed to the step of selecting the plant having a modified content or composition or content and composition, of said metabolite in the storage organ thereof". In addition, it must be noted that Molvig *et al.* contains no disclosure or teaching relating to plants other than lupins.

The Examiner has indicated that she is not in a position to make either a conclusion of "inherency/anticipation" or "obviousness" for the reason that "the record does not allow one to determine if and how the claimed subject matter differs from the prior art". Accordingly, the Examiner suggests that "the burden shifts to Applicant to provide evidence that the prior art would neither anticipate nor render obvious the claimed invention".

Applicants emphasize that, by the Examiner's own admission, Molvig *et al.* is silent with respect to "the claim limitations directed to specific metabolites other than amino acids", and with respect to "the claim limitation directed to the step of selecting a plant". These claim limitations are *not* "certain characteristics or properties claimed" as suggested by the Examiner, they are specific recitals of modification of specific metabolites, and specific method steps. Accordingly, on the

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Examiner's own admission, Applicants respectfully submit that the record clearly indicates how the claimed subject matter differs from the teachings of the prior art.

In view of the foregoing, Applicants respectfully maintain on the record that the invention as claimed is not prima facie obvious over the cited art, and the rejection must be withdrawn.

Conclusion

In view of the foregoing, it is submitted that this case is in condition for allowance, and passage to issuance is respectfully requested.

If there are any outstanding issues related to patentability, the courtesy of a telephone interview is requested, and the Examiner is invited to call to arrange a mutually convenient time.

This amendment is accompanied by a Petition for Extension of Time (three months) and a check in the amount of \$1872.00, including \$930.00 as required under 37 C.F.R. 1.17 for the extension and \$942.00 for the presentation of 15 new claims, including 8 independent claims. It is believed that this amendment does not necessitate the payment of any additional fees under 37 C.F.R. 1.16-1.17. If the amount submitted is incorrect, however, please charge any deficiency or credit any overpayment to Deposit Account No. 07-1969.

Respectfully submitted,



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